UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,111	09/15/2000	Charles J. Davidson	S63.2H-12013-US01	3759

23552 7590 06/07/2006

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/663,111	DAVIDSON ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-8,10-19,42-48,50-70,72 and 73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-8,10-19,42-48,50-70,72 and 73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 September 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: In claims 8, 52, 72, and 73, the "branch stent deployment device" does not have antecedent basis in the specification and it appears to be another manner of claiming the "side member (18)." However, the side member (18) is also claimed so it is unclear what element corresponds to the "branch stent deployment device." See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction is required.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, in claim 8, 52, 72, or 73, the "branch stent deployment device" and the "side member", if they are different elements, must both be shown in the claims.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4, 6-8, 10-13, 15, 18, 45-48, 50-56, 58-60, 63, 65, 70, and 72-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Colombo et al (US 6,520,988) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colombo et al (US 6,520,988) alone. Colombo anticipates the claim language where the markers can be put on all the elements including both dilators and on the side port (19) of the stent; see

column 12, line 52 to column 13, line 20. These markers or indicators are all juxtapositioned in one configuration prior to deployment and located near or at the side port. The side member of Colombo is fixedly attached to the main catheter at least by the stent. The branch stent deployment device as claimed is the balloon portion of the side branch; see Figures 1 to 6. The statement on column 13, lines 11-17 that "the present invention contemplates providing a similar "side port" marker along the other dilator or access devices . . . " meets the limitation requiring a radiopaque marker on the catheter. The Examiner interprets this statement as disclosing that all other elements of the assembly (1) can have radiopaque markers on them.

Alternatively, one could view the markers of Colombo as not being positively juxtapositioned with respect to each other. However, since the markers are to locate the relative position of the stent near the vessel and to detect some change in the configuration, it is the Examiner's position that the putting them adjacent to one another would have been considered clearly obvious to an ordinary artisan.

With regard to claims 8, 52, 72, and 73, the terminology "branch stent deployment device" and the "side member" had been and has been interpreted as part of the same feature as disclosed because "branch stent deployment device" does not have clear antecedent basis from the specification

With regard to claims 50 and 73, it is not clear disclosure that the markers of Colombo are adjacent each other in one configuration and separated in a second configuration. However, since they are separate markers on different elements, they could be considered separated even when they are adjacent each other. Furthermore,

it would have been considered at least obvious to have the markers become more separate in view of Colombo alone because a noticeable change in the configuration was contemplated by Colombo; see column 13, lines 3-20.

Claims 5, 16, 17, 19, 42-44, 61, 62, 64, 66, and 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo et al (US 6,520,988) alone.

Regarding claims 16, 17, 61, and 62, Colombo fails to disclose a balloon inflation lumen, channels, and ports. However, since Colombo discloses balloons that can be inflated by an operator of the device, it would have been obvious to have a lumen with channels and ports to deliver the inflation fluid to the balloons. In other words, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have such features in Duffy because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the a functional set of balloons is all that is necessary. Therefore, it would have been an obvious matter of design choice to modify Duffy to obtain the invention as specified in the claims.

Regarding claims 19 and 64, Colombo fails to disclose the length of the detachment of the elements designated as the catheter and side member. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a 2 to 10 cm detachment length because Applicants have not disclosed that having such provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected

Applicants' invention to perform equally well because it would be suitably sized for the particular bifurcation point. Therefore, it would have been an obvious matter of design choice to modify Colombo to obtain the invention as specified in the claims.

With regard to claim 42-44 and 66-68, Colombo discloses attaching the main and side catheters together with at least the stent but not at some proximal part as claimed. However, since the Colombo teaches attachment of the elements together via the stent, it is the Examiner's position that it would have been obvious to attach the two elements together in some fashion particularly at the proximal end.

Regarding claim 69, Colombo fails to disclose a connector as claimed. However, since the stent performs the same function as a connector and since one could designate one module as the connector, the claimed invention would have been at least prima facie obvious to an ordinary artisan.

Claims 14 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colombo as applied to claims 1, 3, 4, 6-8, 10-13, 15, 18, 45-48, 50-56, 58-60, 63, 65, 70, and 72-73 above, and further in view of Davila et al (US 5,851,464). Colombo fails to disclose the use of pebax and graphite in the catheters. However, Davila teaches that it was known to make catheters out of pebax and graphite; see column 3, lines 8-32. Therefore, it is the Examiner's position that it would have been *prima facie* obvious to make the catheter of Davila out of pebax and graphite for the same reasons that Davila did the same and in order to promote sliding between the catheter and guidewire.

Response to Arguments

Applicant's arguments filed March 16, 2006 have been fully considered but they are not persuasive.

In response to the argument that Colombo does not disclose a marker on the catheter, the Examiner asserts that passage "the present invention contemplates providing a similar "side port" marker along the other dilator or access devices . . . " meets the limitation requiring a radiopaque marker on the catheter; see column 13, lines 11-17. The Examiner interprets this statement as disclosing that all other elements of the assembly (1) can have radiopaque markers on them.

Applicant argues that Colombo does not have the "branch stent deployment device" as claimed in claims 8, 52, 72, and 73. However, the terminology "branch stent deployment device" and the "side member" had been and has been interpreted as part of the same feature as disclosed because "branch stent deployment device" does not have clear antecedent basis from the specification. With this interpretation, the claim language is fully met.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
Primary Examiner
Art Unit 3738